REMARKS

Claims 1-15 remain in the case. Favorable reconsideration is requested.

Claims 1, 3, 4, and 9-13 have been amended herein. Claims 16-18 are newly added herein. The claims as amended enjoy explicit support in the claims as originally filed and throughout the specification. In particular, for sake of consistency, the word "epitope" has been replaced with "antigen" throughout the claims. Use of "antigen" is supported by, for example, Claims 1 and 13 as originally submitted. The amendment of Claim 11 (to read "in which the antigen contains...") is explicitly supported by the language of Claim 12 as originally filed. New Claims 16-18 are supported by original Claims 1-15 as filed and throughout the specification.

No new matter is added.

The follow remarks address the issues presented in the Office Action in the order of their appearance:

Drawings:

Applicant acknowledges that the drawings presently on file are considered informal by the Office. Applicant is currently preparing formal drawings and requests that the requirement for formal drawings be held in abeyance until a Notice of Allowance is issued.

Declaration:

A suitable supplemental declaration, executed by sole inventor Alan Ebringer is attached hereto. Entry of the same is requested.

Abstract:

An Abstract on a separate page is included with this paper.

Withdrawn Rejections:

Applicant's undersigned counsel thanks the Office for noting the withdrawal of the previous rejections under §112, second paragraph, and under §103(a) over the combined teaching of Prusiner et al., Hartnett et al., and Marchalonis et al.

Obviousness-Type Double Patenting:

The rejection of Claims 1, 2, 4-6, and 10-12 for provisional obviousness-type double-patenting in view of application Serial No. 09/269,607, is rendered moot by the duly-executed Terminal Disclaimer filed herewith.

Withdrawal of this rejection is now requested.

Rejection of Claims 1-15 Under 35 USC §112, First Paragraph:

This rejection is believed to have been obviated, in part, by appropriate amendment to the claims, and in light of the objective scientific data presented in the Rule 132 Declaration of inventor Alan Ebringer, submitted herewith. This rejection is also, in part, respectfully traversed.

With regard to the amendments, all of the claims are now limited to a method or a kit for diagnosing "multiple sclerosis, Creutzfeld-Jakob disease, or spongiform encephalopathy in mammals." Insofar as the Office has indicated that the subject matter of the present invention is enabled for these specific disease states, Applicant submits that the amendment largely overcomes this rejection.

With regard to use of the term "spongiform encephalopathy" in Claim 1 (as opposed to "bovine spongiform encephalopathy") Applicant makes the following points:

1) Applicant is not required to submit any working examples to satisfy the enablement requirement. See *In re Robbins*, 166 USPQ 552 (CCPA 1970).

2) Applicant is not required to submit human testing to satisfy the enablement or utility requirements. See, for example, the Guidelines for Examination of Applications for Compliance with the Utility Requirement (first promulgated on 1/31/1995 (1170 O.G. 482): "Data generated using... testing in animals almost invariably will be sufficient to support an asserted therapeutic... utility."

3) Another Prusiner prior art document supplied by the Office in the prosecution of application Serial No. 09/269,607 clearly indicates that spongiform encephalopathy in bovines (*i.e.*, BSE) is transmissible to other mammals, including non-human primates. This document also clearly shows the extremely close relationship between BSE and other forms of spongiform encephalopathy, such as kuru, Creutzfeldt-Jacob disease (CJD), and Gerstmann-Sträussler-Scheinker disease (GSS). Specifically, see page 667 of

the Prusiner paper entitled "Biology and Genetics of Prior Diseases," copy attached as Exhibit C:

> Brain extracts from BSE cattle have transmitted disease to mice, cattle, sheep, and pigs.... Of particular importance in the BSE epidemic is the recent transmission of BSE to a nonhuman primate, the marmoset....

Regarding the very close relationship of BSE to other spongiform encephalopathies, see the opening comments of the Prusiner paper, at page 656:

> A set of remarkable discoveries in the past three decades has led to the molecular and genetic characterization of the transmissible pathogen causing scrapie in animals and a quartet of illnesses in human: kuru, CJD, GSS, and FFI (fatal familial insomnia).

The article goes on to discuss the concept of prions as a unique type or class of proteins. The article also concludes that prions are the causative agent or at least a contributing factor in all of the spongiform encephalopathies discussed in the article (scrapie, BSE, kuru, CJD, GSS, and FFI).

Therefore, because, BSE is transmissible to other species (as shown by the Prusiner article), it is extremely reasonable to conclude that a test that diagnoses spongiform encephalopathy in bovines will also reveal spongiform encephalopathy in other mammals too.

With regard to use of antigens other than the whole Acinetobacter organism, Applicant respectfully traverses this rejection. In support thereof, Applicant submits herewith a Rule 132 Declaration of inventor Alan Ebringer. (Note that Dr. Ebringer's attachment in this paper is unsigned. A signed duplicate will be forwarded as soon as it becomes available. In his declaration, Dr. Ebringer very clearly demonstrates, using objective scientific evidence, that sera from humans suffering from multiple sclerosis contain elevated levels of antibodies specific to *Acinetobacter* spp. Insofar as the specification as filed clearly indicates that the method described therein is applicable to the diagnosis of multiple sclerosis, Dr. Ebringer's declaration provides overwhelmingly convincing evidence that the invention functions exactly as described in the specification, using antigens other than whole *Acinetobacter* species.

In particular, note that Dr. Ebringer's declaration describes fabricating ELISAs to detect antibodies specific to five (5) different species or strains of bacteria of the genus Acinetobacter. See paragraph 8 of Dr. Ebringer's declaration. In comparing 26 patients confirmed to have MS, all 26 patients exhibited significantly increased levels of anti-Acinetobacter antibodies as compared to normal controls. This included increased levels of IgA, IgG and IgM anti-Acinetobacter antibodies.

The ELISAs described in Dr. Ebringer's declaration were read in blind format, with the experimenter gathering the results not knowing whether the samples being measured were test samples or control samples. Note also that the experiments presented in Dr. Ebringer's declaration were also deemed suitable for publication, and have, in fact, appeared in a peer-reviewed journal article (which has been made part of Dr. Ebringer's declaration).

Additionally, paragraph 12 of Dr. Ebringer's declaration describes an experiment in which the polypeptide QNF**ISRFAWGEV**NSR was used as the test antigen. The underlined residues correspond to SEQ. ID. NO. 2 of the present application. This experiment clearly shows that the invention disclosed in the application functions not only with whole Acinetobacter species, but isolated antigen take from the Acinetobacter.

The data presented in Dr. Ebringer's declaration clearly indicate that the subject invention, as described in the specification as filed, functions to indicate the presence of CJD, MS, and spongiform encephalopathy in a mammalian test subject, using isolated antigens derived from Acinetobacter.

In light of the amendment to the claims, and the Rule 132 Declaration of Dr. Ebringer submitted herewith, Applicant respectfull submits that the rejection of Claims 1-15 under §112, first paragraph, is no longer tenable. Withdrawal of the same is respectfully requested.

CONCLUSION

Applicant submits that the application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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